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DOCKET NO.: P0453.70116US01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Sanghvi et al.  
Serial No.: 10/821,809  
Confirmation No.: 9063  
Filed: April 8, 2004  
For: COMBINATION THERAPY FOR CONSTIPATION  
Examiner: Phyllis G. Spivack  
Art Unit: 1614

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 20<sup>th</sup> day of February, 2007.

*Emily E. Zukauskas*  
Emily E. Zukauskas

MAIL STOP AMENDMENT

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,

By: *Edward R. Gates*  
Edward R. Gates, Reg. No. 31,616  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
Telephone: (617) 646-8000

Docket No.: P0453.70116US01  
Date: February 20, 2007  
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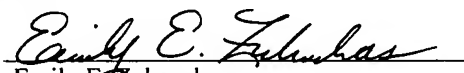
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Emily E. Zukauskas

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**MAIL STOP AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing of a first Office action on the merits in the above-identified case.

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified PTO/SB/08). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>	<u>Docket No.</u>
11/441,395	May 25, 2006	Doshan	*P0453.70119US01
11/441,452	May 25, 2006	Wagoner et al.	*P0453.70120US02

\*A copy of this reference is not provided as the Office has waived the requirement under 37 C.F.R. 1.98(a)(2)(iii) for submitting a copy of each cited U.S. patent application if they are scanned to Image File Wrapper system and are available on Private PAIR.

The Applicant would like to bring to the Examiner's attention the enclosed search report or other communication from a corresponding International or Foreign National Application.

<u>Serial No.</u>	<u>Mailing Date</u>	<u>Type(s) of Communication</u>	<u>Docket No.</u>
SG 200506462-1	April 27, 2006	Written Opinion	P0453.70116SG00

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 (modified PTO/SB/08) be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;

3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

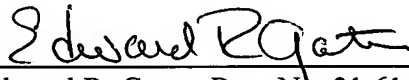
By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his or her own conclusion regarding the relevance of the cited information.

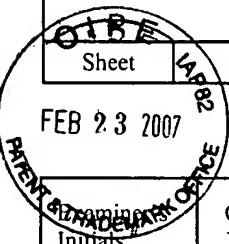
An early and favorable action is hereby requested.

Respectfully submitted,

By:   
Edward R. Gates, Reg. No. 31,616  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
Telephone: (617) 646-8000

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FORM PTO-1449/A and B (modified PTO/SB/08)  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		APPLICATION NO.: 10/821,809	ATTY. DOCKET NO.: P0453.70116US01
		FILING DATE: April 8, 2004	CONFIRMATION NO.: 9063
		APPLICANT: Sanghvi et al.	
		GROUP ART UNIT: 1614	EXAMINER: Phyllis G. Spivack
Sheet 1 of 4			



### U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
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		2006-0205753	A1	Israel	09-14-2006

### FOREIGN PATENT DOCUMENTS

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
		DE	196 51 551	A1	Klinge Pharm GmbH	06-18-1998	Y-Abstract
		EP	0 289 070		Duphair International Research B.V.	11-02-1988	

EXAMINER:	DATE CONSIDERED:
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# EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

<b>FORM PTO-1449/A and B (modified PTO/SB/08)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 10/821,809		ATTY. DOCKET NO.: P0453.70116US01	
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Sheet	2	of	4				

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		WO	2004/091623	A1	Progenics Pharmaceuticals, Inc.	10-28-2004	

**OTHER ART — NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
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		YUAN et al., Pain control with side effects: clinical studies on methylnaltrexone as a novel peripheral opioid antagonist. 7 <sup>th</sup> America-Japan Anesth Congr. Yamanashi, Japan. 2002:41.	

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_, filed \_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE – No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR §1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR §1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR §1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. §120.]

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